DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6009

9/0841d

March 27, 2001

WARNING LETTER

CERTIFIED MAIL –
RETURN RECEIPT REQUESTED

Mr. Scott Tourville
President
Zeus Scientific, Inc.
200 Evans Way
Branchburg, New Jersey 08876

File No.: 01-NWJ-21

Dear Mr. Tourville:

During an inspection of your firm located in Branchburg, New Jersey, from January 16-31, 2001, investigators from the Food and Drug Administration (FDA) determined you manufacture IVD test kits, which are medical devices within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above referenced inspection determined your firm is not in compliance with applicable regulations concerning medical devices, specifically, deficiencies were noted with the documentation system used to record corrective and preventive actions for non-conforming devices. Your firm failed to comply with section 502(t)(2) of the Act, specifically, failure to follow reporting requirements found in Title 21 Code of Federal Regulations (CFR), Part 806, as follows:

Your firm recalled Toxo IgM ELISA kits, product number 1029-315Z, Lots 1S+T010880 and 8 TOXO02918, in April 1999, due to high false positive rates. However, you failed to notify the agency within 10 working days of initiating this corrective action, which was later determined to be a Class II recall, not a Class III, as initially assessed. Furthermore, the records of removals fail to justify the rationale not to report this removal to the FDA, especially since your firm was cited during an inspection one month prior to this incident for not reporting a recall of the same product line for a similar occurrence.

In addition, your procedure for handling such events, QS 100P04, Rev 0, Removal and Corrections, does not require notification of the FDA when a Class II removal or correction occurs, other than MDR reportable events.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

In addition to the above, your firm failed to validate the electronic documentation system used to record corrective action requests (CARs) prior to implementation. The electronic record requires electronic signature, for which there is no timestamp on the record. Also, you failed to certify to the FDA that the electronic signatures are legally binding. We have received your written request, dated February 6, 2001, in which you state this system was in validation mode at the time of the inspection. There was no indication during the inspection that the CARs system was being validated. In fact, there was no evidence that a concurrent manual system was in place for recording CARs. Your procedure, SOP-0017 indicated the electronic forms were in effect since July 2000.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken toward corrective action, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be directed to the New Jersey Office, FDA, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 070054, Attn: Mercedes Mota, Compliance Officer.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District